

Still further, the Office Action requires election to one of the bacterium or virus antigen species, in claims 3, 13 and 22, which are said to be structurally, functionally and immunologically distinct and also patentably distinct

It is the position of the Examiner, in item 4, that the inventions (I, II, III) are distinct from one another, that inventions II and III are directed to independent and distinct methods which differ from each other in the method steps and ultimate goals accomplished.

It is the Examiner's further position that inventions I and II, as well as invention I and III, are related as product and process of using the product, and that inventions can be shown to be distinct if either or both of the following can be shown:

- (1) the process of using the product as claimed can be practiced with another materially different product, or
- (2) the product as claimed can be used in a materially different process of using that product.

According to the Examiner, in the instant case, the bacterial or viral antigen can be used in a materially different process, for example in an *in vitro* diagnostic assay. The Examiner continues, "[b]ecause these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classifications/subclassifications and divergent subject matter, restriction for examination purposes.

Initially, it must be noted that the restriction requirement is not capable of being understood in that invention I is said to be classified in class 530, subclass 825/826, which is defined in the manual of Classification as,

CLASS 530. CHEMISTRY: NATURAL RESINS OR DERIVATIVES; PEPTIDES OR PROTEINS; LIGNINS OR REACTION PRODUCTS THEREOF

825 Bacteria:

This subclass is indented under subclass 820. Cross-reference art collection for peptides or proteins which are separated from bacteria.

826 Viruses: This subclass is indented under subclass 820. Cross-reference art collection for peptides or proteins which are separated from virus.

whereas invention II is said to be classified in class 424, subclass 93.1, which is defined in the Manual of Classification as,

93.1 WHOLE LIVE MICRO-ORGANISM, CELL, OR VIRUS CONTAINING: This subclass is indented under the class definition. Subject matter involving a whole and living micro-organism, cell, or virus or its spore form.

(1) Note. Utilities such as pest control, warfare, disease eradication, etc., are included in this subclass and indented subclasses.

(2) Note. Included under the heading micro-organism, cell, or virus are bacteria, actinomycetales, fungus, protozoa, alga, plant cell, animal cell (includes a specified blood cell or tissue cell), and virus.

(3) Note. If there is no clear disclosure to the contrary, lyophilized micro-organisms, cells, or viruses are considered alive and are therefore appropriate for this subclass or indented subclasses.

(4) Note. If there is no clear disclosure as to whether the whole micro-organism, cell, or virus is alive or dead, it shall be presumed to be alive and therefore appropriate for

subclass 184.1 of class 424, defined by the Manual of Classification, as follows:

184.1 ANTIGEN, EPITOPE, OR OTHER IMMUNOSPECIFIC IMMUNOEFFECTOR (E.G., IMMUNOSPECIFIC VACCINE, IMMUNOSPECIFIC STIMULATOR OF CELL-MEDIATED IMMUNITY, IMMUNOSPECIFIC TOLERAGEN, IMMUNOSPECIFIC IMMUNOSUPPRESSOR, ETC.): This subclass is indented under the class definition.

Subject matter involving an antigen, an epitope, or another immunospecific immunoeffector, such as an immunospecific vaccine, an immunospecific stimulator of cell-mediated immunity, an immunospecific toleragen, or an immunospecific immunosuppressor.

(1) Note. An antigen is a substance that elicits the production of antibodies, wherein the antibodies then have binding specificity for that antigen.

(2) Note. An epitope is a portion of an antigen to which an antibody binds. An epitope is also called an antigenic determinant.

(3) Note. An immunospecific immunoeffector, for the purposes of this subclass and indented subclasses, is a substance that induces a specific immunological effect (e.g., specific immunity to polio), whether it be immunospecific immunity, immunospecific tolerance, or immunospecific immunosuppression.

(4) Note. This subclass and indented subclasses provide for bioaffecting and body-treating compositions of antigens, epitopes, and other immunospecific immunoeffectors.

(5) Note. This subclass and indented subclasses also provide for bioaffecting and body-treating methods of using antigens, epitopes, and other immunospecific immunoeffectors and compositions thereof.

(6) Note. This and the indented subclasses provide for methods of immunizing to produce protective immunity in vivo (i.e., for vaccination purposes).

SEE OR SEARCH THIS CLASS, SUBCLASS:

93.1+, for a nonimmunologic bioaffecting or body-treating composition containing a whole live micro-organism, cell, or virus.

130.1+, for methods of immunizing with an antigen to produce antibodies for recovery, which antibodies are characterized as being useful as bioaffecting or body-treating agents (e.g., to provide passive immunity).

538+, for bee or other insect or arachnid venom for which there is no specific disclosure that it functions as an antigen.

542, for snake venom for which there is no specific disclosure that it functions as an antigen.

It is nevertheless unclear to applicants where the distinction or the purported classification definition between the methods distinguished by the Examiner as invention II and III resides or is found.

Applicants emphatically traverse the requirement; however, as required, provisionally elect the prosecution of the claims of Group II, namely Claims 1-10, the bacterium of claim 11 and the porcine antigen, *Erysipelothrix Rhusiopathiae* found in claim 13.

Under 35 U.S.C. 121 "two or more independent and distinct inventions ... in one application may ... be restricted to one of the inventions." Inventions are "independent" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related ... but are capable of separate

manufacture, use or sale as claimed, and are patentable over each other" (MPEP 802.01). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Under Patent Office examining procedures, "If the search and examination of an entire application can be made without serious burden, the Examiner is encouraged to examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988).

In the present instance, the central aspect of all the claims is a vaccine composition comprising an antigen, a water soluble palatable flavorant and a water soluble vehicle. It would therefore follow that a search directed to such compositions would extend to the relevant areas of classification where the use of such compositions would be searched would be searched. In view thereof, Applicants urge that the restriction be withdrawn and that all of the claims of record by examined simultaneously.

Further thereto, The examiner's attention is called to the directions recorded in the Manual of Classification and referred to above. For example, the Manual under 424/93.1, wherein invention II was classified in the Office Action, directs that 424/184.1 (the presumed class and subclass for invention III) should be seen and searched. The opposite direction is similarly given by the Manual with respect to 424/93.1 under 424/184.1. This shows that both these classifications would/should necessarily be searched and the classifications are merely, or very often, just a convenience.

Moreover, the heading of 424/184.1 refers to "Antigen" which does not distinguish between an antigen which is bacterial or viral in origin, the separation provided by subclasses 826 and 825 of class 530. It is obviously useful to have classifications which may well aid and facilitate searching, but the classifications do not categorically support a finding that the invention claimed should therefore be restricted.

Examples abound of granted US patents that contain multiple claim forms and multiple species which have gained separate classifications. To cite just a few examples, see US Patents:

- 6,197,301 - containing claims to these varieties: a polypeptide, a fusion protein, a vaccine, a method of treating and preventing ..., a diagnostic kit, a method for detecting... This patent included a field of search (under current classifications) encompassing 5 subclasses of 424; 5 subclasses of 530; 5 subclasses of 435; 1 subclass of 536; and one subclass of each of 436 and 514.
- 5,871,150 - containing claims to a vaccine composition and a method, including a field of search (under current classifications) encompassing 9 subclasses of classes 424, 435 and 530.
- 5,871,748 - containing claims to a method of producing active immunity ..., a vaccine preparation, an article of manufacture ..., including a field of search (under current

classifications) encompassing 7 subclasses of classes 424, 530 and 435.

- 6,261,569 - containing claims to a synthetic peptide antigen, a method of preparing such an antigen, a method of preparing an immunogenic composition and a method of inducing antibodies, including a field of search (under current classifications) encompassing 18 subclasses of classes 424, 530 and 514 - and including specifically, inter alia, 424/184.1, 530/825 and 530/826.
- 6,030,618 containing claims to a composition, a method of eliciting an immune response, a kit, including a field of search (under current classifications) encompassing 2 subclasses of classes 424, 530 and 514 - and including specifically, inter alia, 424/184.1, 530/825 and 530/826.

For the above reasons, Applicants request withdrawal of the Requirement for Restriction, and early action on the merits as to all of the claims presently pending in the case,

No fees are believed to be due for this response. However, should this be in error, authorization is hereby given to charge Deposit account No. 01-1425.

Respectfully submitted,



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